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EXAMINER

FIDEI, DAVID

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 04/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-8 and 27-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Nothing is set forth in the present disclosure defining a peelable, or non-peelable force, as one that can be separated by the normal application of manual force by a user's hand.

Additionally, nothing is expressed in the present application that the package is rendered useless should the coil portions be detached from one another.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 1-8 and 27-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The scope and content of a "non-peelable" relationship that is of a character incapable of separation by normal manual force of a user's hands, or that results destruction of the package, is not defined.

The examiner's reviewing authority has stated that the second paragraph of 35 U.S.C. 112 requires a claim to particularly point out and distinctly claim the subject matter which applicant regards as his or her invention. Under *In re Hammack*, 166 USPQ 204 (CCPA 1970) and *In re Moore*, 169 USPQ 236 (CCPA 1971), claims must be analyzed to determine their

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metes and bounds so that it is clear from the claim language what subject matter the claims encompass. This analysis must be performed in light of the applicable prior art and the disclosure. The definiteness of the claims is important to allow others who wish to enter the market place to ascertain the boundaries of protection that are provided by the claims. *Ex parte Kristensen*, 10 USPQ 2d 1701, 1703 (PTO Bd. Pat. App. & Intf. 1989).

The silence of the application in this regard fails to meet the requirements of 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-3 and 27-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prather et al (Patent no. 5,247,942) in view of Globensky et al (Patent no. 6,511,573). Prather et al discloses a package for an elongate surgical device comprising an elongate tube 16 held¹ in a coiled condition by clips 18 or any other suitable means, col. 4, lines 43, 44.

The difference between the claimed subject matter and Prather et al resides in a weld bond fixing a first coiled portion to a second coil portion of the coil. Globensky et al discloses holding adjacent tubes by a “weld bond” where a filler material is melted to a liquid state and hardens as a fastener, e.g., see col. 4, lines 43-51.

It would have been *prima facie* obvious to one skilled in the art at the time the invention was made to modify the coil of Prather et al by employing weld bonding for holding the tube in the coiled configuration, for the reason that such means of holding is shown by the prior art to be an obvious expedient manner of maintaining a coil. The motivation for the combination is found

¹ Past tense and past participle of hold; “To keep from falling or moving”, dictionary.com

in Prather et al, col. 4, lines 43, 44 where it is recognized other suitable means are envisioned to hold the tube in the coiled configuration.

As to the newly added subject matter of the bond being a fixed, non-peelable relationship, this appears to be contemplated by the prior art within the ordinary meaning of the terms used to describe the coiled relationship. To the extent that peeling or detaching the package of Prather et al does not render it useless, to construct the package bonded as such would have been within the level of ordinary skill in order to maintain the coils integrity while rendering the package unusable upon a comprise of such integrity.

As to claims 2 and 27, the heating of the adhesive material to hold the tube in place is considered a thermal weld.

As to claims 3, 28, 31 and 32, the tube of Globensky et al, embodies a continuous weld is shown in the transverse section of figures 2, 13 and 19, that can be construed as a separate bridge bond intermittently applied around the circumference of the coil.

As to claim 29, the tube of Prather et al and the bridge bond of Globensky et al being composed of a common material. Prather et al contemplates a polyolefin in col. 4, line 40 while Globensky et al discloses a polypropylene in col. 4, line 43. Polyolefins is the collective name for polyethylene (PE) and polypropylene (PP) - among the most widely used plastics today.²

As to claim 30 the coils of both Prather et al and Globensky et al are in a common plane as shown in figures 1 and 7, respectively.

As to claim 33, a package is set forth similar to claim 1, except that a second elongate tube is set forth having the same features of the first elongate tube. In this regard, nothing is defined concerning the relationship of the tubes, nor is any package structure set forth. It would have been obvious to one skilled in the art at the time the invention was made to construct a second tube of Prather et al similar constructed as the first tube, in order to provide mass production of surgical guide wires.

As to claim 34, thermal welds are formed as discussed above.

² Source; www.borealisgroup.com/public/about/what/polyolefins.html

As to claim 35, stacking coiled tubes as claimed is taken to be within the level of ordinary skill, as one would stack hoses or tires. To provide a first and second coil stacked as claimed would have been obvious for the reason of storing the packages after fabrication, prior to shipment or for storage at the surgical facility.

7. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over the prior art as applied to the claims above, and further in view of Jaeschke et al (Patent no. 4,332,322). The difference between the claimed subject matter and Prather et al resides in a backing card carrying the tube in the coiled configuration. Jaeschke et al discloses a container for packing a coil of plastic tubing that comprises a folder with a backing card. Jaeschke et al, col. 3, lines 35-37 contemplates a sealed pouch to be used with the folder.

To provide the coiled tube of Prather et al with a carrying backing card in a sealed pouch would have been a well-recognized manner of forming a sterile surgical package.

As to claim 6, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the folder of paper, a paper laminate or olefin, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

8. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over the prior art as applied to the claims above, and further in view of Farrell et al (Patent no. 6,053,313). The difference between the claimed subject matter and Prather et al resides in a retaining accessory coupled to the first end of the elongated tube.

Farrell figure 1, discloses a clip D coupled to the first end of the tube, see col. 3, lines 45-49. It would have been obvious to one skilled in the art at the time the invention was made to include retaining accessories coupled to the first end of the tube as taught by Farrell et al, in order to provide accessories need for the surgical procedure.

As to claim 8, the material used for the accessories would have been an obvious matter of design choice for the reason listed in the previous paragraph.

Response to Arguments

9. Applicant's arguments with respect to claims 1-8 and 27-35 have been considered but are moot in view of the new ground(s) of rejection.

The claims have been amended to define the bonds holding the coiled tube together as "non-peelable". By peelable applicant refers to the normal application of manual force by a user's hand, e.g., see page 8 of remarks. However, this qualifies the term over that set forth in the application as originally filed. Upon re-reading the application, nowhere is anything set forth prescribing "peelable" in the terms of normal manual forces by a user's hands. Indeed, it is not even clear what the scope of this force may be. In the closure art caps are often constructed to compensate for the manual dexterity of individuals. Particularly elderly, disabled, or physically impaired individuals. These parameters are not defined in by the present invention in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Nor does the present application make it clear that this what the intent of the language.

Similarly, applicant's assertion that the weld is of sufficient strength that detaching the coiled portions from each other would break the package beyond use is also not illustrated. Accordingly, the claims have been rejected as indicated above.

As to the art applied to merits of the re-drafted claims, there is no indication in either Prather et al or Globensky et al that the intent is to provide a peelable bond. In fact the clips, or other suitable means, of Prather et al are indicated in the bottom of page 1 of the present application as endeavor "to maintain the coiled configuration of the tube". Accordingly, it is submitted the differences between the claimed subject matter and Prather et al are such that they would have been obvious to one of ordinary skill in the art at the time of the present invention.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fidei whose telephone number is (571) 272-4553. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The Official Fax number to file responses to this Office Action is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David T. Fidei
Primary Examiner
Art Unit 3728

Dtf
April 11, 2006